

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) and
Drug Safety & Risk Management Advisory Committee (DSaRM)

**Holiday Inn, the Ballrooms, Two Montgomery Village Avenue, Gaithersburg, Maryland
September 23, 2009**

AGENDA

The committee will discuss new drug application (NDA) 21-217, EXALGO (hydromorphone HCl), Neuromed, Inc., and its safety for the proposed indication of treatment of moderate-to-severe pain in opioid tolerant patients

8:00 a.m. Call to Order
Introduction of Committee

Jeffrey Kirsch, M.D.
Chair, ALSDAC

Conflict of Interest Statement

Kalyani Bhatt,
Designated Federal Officer, ALSDAC

8:10 a.m. Opening Remarks

Clinical Team Leader
Division of Analgesia, Anesthesia, and
Rheumatology Products (DAARP), CDER, FDA

Sponsor Presentation

Neuromed, Inc.

8:15 a.m. Introduction

Presentation 1

Presentation 2

Presentation 3

9:45 a.m. Questions for Presenters

10:05 a.m. **Break**

FDA Presentation

10:20 a.m. Clinical Review of EXALGO

Medical Officer
DAARP, CDER, FDA

10:40 a.m. Drug Utilization Trends

Drug Utilization Analyst
Division of Epidemiology (DEPI)
OSE, CDER, FDA

10:50 a.m. Findings from the Drug Abuse Warning
Network (DAWN)

Epidemiologist
Division of Epidemiology (DEPI),
OSE, CDER, FDA

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11:10 a.m. EXALGO Abuse Liability

Medical Officer
Controlled Substance Staff (CSS), CDER, FDA

11:25 a.m. EXALGO Risk Management: Postmarketing
Experience and Recommendations

Risk Management Analyst
Division of Risk Management
OSE, CDER, FDA

11:40 a.m. Questions for Presenters

12:00 p.m. **Lunch Break**

1:00 p.m. Open Public Hearing

2:00 p.m. Discussion/Questions to the Committee (Vote)

4:30 p.m. **Adjourn**